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**MOLECULAR AND CLINICAL GENETICS PANEL**  
***AGENDA******March 27, 2014***  
**Molecular and Clinical Genetics Panel**  
**Exact Sciences Corporation**  
***Cologuard***  
***Hilton Washington DC North/Gaithersburg***

On March 27, 2014, the committee will discuss, make recommendations and vote on information related to the premarket approval application for the *Cologuard* device, sponsored by Exact Sciences. *Cologuard* is an in vitro diagnostic device designed to analyze patients' stool for detection of hemoglobin, multiple DNA methylation and mutational markers, and the total amount of human DNA. *Cologuard* is intended for use as an adjunctive screening test for the detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer or premalignant colorectal neoplasia. *Cologuard* is not intended as a replacement for colonoscopy. *Cologuard* is intended to be used in conjunction with colonoscopy and other test methods in accordance with recognized screening guidelines.

8:00 a.m.	Call to Order Introduction of Committee	Chairperson
	Conflict of Interest Statement	<b>Jamie Mae Waterhouse, M.B.A.</b> Designated Federal Officer
8:15 a.m.	Sponsor Presentation	
9:30 a.m.	Sponsor Q&A	
9:45 a.m.	Break	
10:00 a.m.	FDA Presentation	
11:15 a.m.	FDA Q&A	
11:30 p.m.	Lunch	
12:30 p.m.	Open Public Hearing	
1:30 p.m.	Panel Deliberations	
2:15 p.m.	Break	
2:30 p.m.	FDA Questions to the Panel	
4:00 p.m.	FDA and Sponsor Summations	
4:30 p.m.	Panel Vote	
5:00 p.m.	Adjournment	

**\* Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.